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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,902	07/25/2003	Brian Blischak	02-029 CIP	2425

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EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,902	BLISCHAK ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/25/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant elected the claims of Group II for further prosecution in this application without traverse.

Applicant has cancelled the non-elected claims from the application without prejudice in the reply received October 5, 2006.

Specification

The disclosure is objected to because of the following informalities: in paragraph 25, the section beginning ". . . which includes an occlude the outlet flow path . . ." is unclear.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16, 17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haerton et al (US 4,077,405) in view of Bui (US 6,986,732) and further in view of Woias et al (US 6,129,702).

Haerton discloses a method for infusing a fluid in a living body comprising providing a reservoir (1), a flow restrictor (19) and a valve (4) in an implantable drug pump (col. 4 line 45); transiently storing a fluid infusate in the reservoir for transmission to a delivery site after the implantable drug pump device has been implanted in a patient; limiting flow rate of the fluid infusate using the flow restrictor (19) disposed in a fluid path between the reservoir and the delivery site (see fig. 1).

Haerton et al fails to disclose determining transient pressure differentials, an alert or detecting an occlusion.

Bui et al discloses a similar method including determining transient pressure differentials relative to the flow restrictor by a controller component (36); determining whether an occlusion is present in the flow path using transient pressure differentials and controlling the valve disposed in the fluid path between the reservoir an the delivery site to control infusate output from the reservoir to the delivery site as a function of transient pressure differentials across the flow restrictor, determining a rate at which a pressure differential across the flow restrictor changes, altering timing of a period of the valve being opened as a function of the rate at which a pressure differential across the flow restrictor changes (col. 3 line 45-col. 4 line 4) and providing an alert with respect to

overfilling or depletion of the reservoir using pressure differential across the flow restrictor (col. 3 line 56).

Woias et al discloses a similar method including altering the unit dose and determining temperature and altering infusate output based on infusate temperature (col. 5 lines 58-65; col. 3 line 29).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the method of Haerton by adding the steps of altering unit dosage based on pressure differentials and infusate temperature of the type taught by Bui and Woias, in order to deliver fluid at in a more controlled or efficient manner.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haerton et al (US 4,077,405) in view of Bui (US 6,986,732) and further in view of Woias et al (US 6,129,702) and further in view or Alt (US 5,342,404).

Haerton in view of Bui and Woias disclose the method above in reference to claim 17, but do not explicitly disclose that the unit dose periods are selected at least in part to reduce battery consumption.

Alt et al disclose a method in which a delivery of a therapeutic dose is based in part to reduce battery consumption (col. 10 line 35).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Haerton in view of Bui and Woias by adding the step of selecting dose increments to reduce battery consumption as taught by Alt et al in order to battery lifetime of the implanted device (col. 10 line 47).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-24 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,620,151. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art to include detecting occlusion as a form of catheter malfunction as claimed in the issued patent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Burkett US 5103211 A discloses a method of detecting fluid flow occlusion by using measuring and calculating fluid flow differentials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Ahmed

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER